

**K171868 A1AT Genotyping Test**Nov 11, 2017  
142 days to decisionK171868 · Product code: **PZH** · Immunology  
Source: <https://www.510kdatabase.net/k171868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Serpina1 Variant Detection System (PZH)
Date received	Jun 22, 2017
Decision date	Nov 11, 2017
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Progenika Biopharma S.A., A Grifols Company</b>
Location	Derio, ES
Contact	Diego Tejedor
510(k) history	4 submissions · 4 cleared · 2017-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171868/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026